SECTION 5 – 510(k) SUMMARY K062147

[Submitted pursuant to 21 CFR 807.92(a). All data included in this document are accurate and complete to the best of DSC's knowledge.]

1. Submitter Information

OCT 20 2006

Submitter:	Direx Systems Corporation 437 Turnpike Street Canton MA 02021
Telephone:	(339) 502-6013
Fax:	(339) 502-6018
Contact Person	Larisa Gershtein QA Manager
Contact Person e-mail address:	lgershtein@direxusa.com

2. Device

Trade/Proprietary Name:	Integra SL
Common/Usual Name:	Extracorporeal Shock Wave Lithotripter (ESWL)
Regulation Number:	21 CFR 876.5990
Regulatory Class:	Class II (special controls)
Product code:	78 LNS
Panel:	Gastroenterology and Urology

3. Predicate Devices

Direx Integra (K053640)

Direx Tripter X – 1 Compact Duet (K041582)

4. Intended Use:

Integra SL is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and upper ureter.

5. Description

Integra SL is a transportable Electromagnetic (EM) Extracorporeal Shock Wave Lithotripter (ESWL) used for urinary stones treatment. The device consists of a Shock Wave Generator (SWAG), a Urological Table (UT) and the remote controls. *Integra SL* also contains the necessary interfaces for fluoroscopic and (or) ultrasonic imaging devices. The device has no Software control.

Integra SL includes the following features:

- EM Shockwave generator with parabolic reflector for focusing mechanism
- Swinging reflector (i.e. shockwaves are produced by angularly moving the shockwave while keeping the Therapeutic focus (F2) at the stone such that the shockwaves converge on the stone from multiple orientations).
- A stand alone UT unit
- Modular construction

6. Clinical Tests

No clinical tests were performed

7. Performance Testing

Integra SL was tested according to the following standards:

- IEC 60601-1 (1988) +A1 (1991) +A2 (1995)
- IEC 60601-1-1 (2000)
- IEC 60601-1-2 (2001)
- IEC 606001-2-36 (1997)
- IEC 61846 (1998)
- IEC 60601-2-46 (1998)
- ANSI/ AAMI/ ISO 10993– 1 (1998)

- Guidance for the Content of Premarket Notifications (510(k)s) for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi; August 9, 2000

7. Substantial Equivalence

Integra SL is meets the requirements for a special 510(k) by the virtue of being a minor modification, which does not change the fundamental technology or reduce safety and effectiveness, of the Company's predicate device, *Integra*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Larisa Gershtein
QA Manager
Direx Systems Corp.
437 Turnpike Street
CANTON MA 02021

OCT 20 2006

Re: K062147
Trade/Device Name: Integra SL
Regulation Number: 21 CFR 876.5990
Regulation Name: Extracorporeal shock wave lithotripter
Regulatory Class: II
Product Code: LNS
Dated: September 21, 2006
Received: September 22, 2006

Dear Ms. Gershtein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DiREX
SYSTEMS CORP.

Section 4: Indications for Use Statement

Indications for Use STATEMENT

510(k) Number (if known): K062147

Device Name:

Integra SL

Indications for Use:

Integra SL is intended to fragment urinary stones in the kidney (renal pelvis and renal calyces) and upper ureter

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR § 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062147

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